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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,235	07/13/2001	Jeffrey A. Robl	LA 24B Contl	3904

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EXAMINER

MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/905,235	ROBL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Abdel A. Mohamed	1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                 | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4,6,7,8,9</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

#### **ACKNOWLEDGMENT OF PRIORITY, PRELIMINARY AMENDMENT, SEQUENCE LISTING, IDS, RESPONSE TO THE RESTRICTION REQUIREMENT, STATUS OF THE APPLICATION AND CLAIMS**

1. This application is a Continuation of Application No. 09/390,275 having a filing date of 9/7/99, now abandoned, which claim benefit of Provisional Application 60/100,677 having a filing date of 9/17/98. The preliminary amendment and sequence listing filed 7/13/01; the information disclosure statements (IDS) and Form PTO-1449 filed 9/20/01, 9/30/02, 10/31/02, 12/2/02 and 5/19/03; and the response to the restriction requirement filed 10/24/03 are acknowledged, entered and considered. Claims 1-20 are now pending in the application.

#### **ELECTION WITHOUT TRAVERSE**

2. Claims 1-20 were originally filed. The claims were subject to a Restriction Requirement/Species Election in the Office action mailed 9/24/03, Paper No. 10. Applicant re-affirmed the election of Group I (claims 1-15) and species of Group XVI as currently amended in claim 14 with the ultimate species being the structure of claim 15 as currently amended in claim 15 without traverse by stating that Applicant has already chosen a group and species in provisional election based on the Restriction/Election requirements previously entered in parent application Serial No. 09/390,275. Applicant indicated that claims 1-10, 12, 14 and 15 read on the elected species and requested that the examination be conducted on the elected claims.

However, Applicant also traversed the restriction requirement by stating that Groups I and II would not require multiple searches, but only a search on an aP2 inhibitor, the concept common to both the method and pharmaceutical compositions of Groups I and II. Accordingly, a search on the claims would not unduly burdensome and the entire application should be searched. Contrary to Applicant's traversal, Group I is drawn to a method for treating atherosclerosis by administering an aP2 inhibitor while Group II is drawn to a pharmaceutical combination comprising an aP2 inhibitor and another type antiatherosclerosis agent. Thus, the inventions as grouped are independent and distinct inventions, which differ in material make up, and formulations requiring different reaction condition and effect. Hence, one does not require the other for ultimate use and as such is capable of separate manufacture, use and sale, and is novel and patentable over each other. Therefore, claims 16-20 (Group II) is withdrawn as non-elected invention for the reasons discussed above; thus, the Office action is directed to the merits of claims 1-15 as per elected invention.

The requirement is still deemed proper and is therefore made FINAL.

In response to the above Final, Applicant is advised to cancel the non-elected invention.

### **CLAIMS REJECTION-35 U.S.C. § 112<sup>2nd</sup> PARAGRAPH**

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is indefinite in the recitation "...are selected from....", "...is selected from...." and ".....a member selected from....." because it is not clear if Applicant intends a Markush format. If Applicant intends to use a Markush format, then, the Office recommends the use of the phrase "...selected from the group consisting of....." with the use of connective words such as "and" or "or" in listing species.

Claim 14 is also indefinite in the recitation "optionally" because if an ingredient, a step, or other structural element is truly optional i.e. its presence is not necessary for attainment of the result that is an object of the invention, then recitation thereof does not belong in the claims.

#### **CLAIMS REJECTION-35 U.S.C. 102(b)/103(a)**

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any one of the following references of WO 92/04334, Romine et al. (U.S. Patent No. 5,348,969), Meanwell (U.S. Patent No. 5,362,879) and Murugesan (U.S. Patent No. 5,612,359).

Each one of the references cited above treat atherosclerosis by using an oxazole derivative (See e.g., page 6 of WO 92/04334; col. 1, line 21 of '969 patent; col. 1, line 33 of '879 patent; and claim 25 of '359 patent, respectively). Also, see each cited document in its entirety. Because the claims are drawn to a method of treating atherosclerosis using an active therapeutic compound, which is an oxazole derivative thereof, the claims are anticipated and/or rendered obvious over the cited art.

Note: the Examiner is not in a position to establish the mechanism of action for a therapeutic compound, i.e., use of the therapeutic compound in a method of treating a subject; hence, the burden is on the Applicant to show the differences, if any. In any event the discovery of the mechanism for the action of **a therapeutic compound** in a

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treatment method does not render patentability to the **same therapeutic compound** used in the same method.

### **ALLOWABLE SUBJECT MATTER**

5. Claims 14 and 15 as currently amended would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 102(b)/102(a) set forth in this Office action and to include all of the limitation of the base claim and any intervening claims.

### **REASONS FOR INDICATION OF ALLOWABLE SUBJECT MATTER**

6. The following is an Examiner's statement of reasons for the indication of allowable subject matter: The specific and ultimate species as described in claims 14 and 15 were not found in the prior art of record in the manner claimed.

### **CONCLUSION AND FUTURE CORRESPONDENCE**

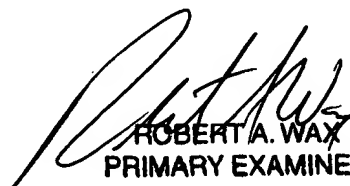
7. Claims 1-15 are rejected and claims 16-20 are withdrawn as non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



ROBERT A. WAX  
PRIMARY EXAMINER

 Mohamed/AAM

January 7, 2004